B BRAUN
SHARING EXPERTISE

February 10, 2020

Environmental Protection Agency
EPA Docket Center (EPA/DC)
Mail code 28221T
Attn: Docket ID No. EPA-HQ-OAR-2019-0178
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Advance Notice of Proposed Rulemaking
40 CFR Part 63, Subpart O
EPA Docket No. EPA-HQ-OAR-2019-0178

Dear Sir or Madam:

B. Braun Medical Inc. (B. Braun) operates a medical device manufacturing facility at 901 Marcon Blvd. in Allentown, Pennsylvania (Facility). B. Braun sterilizes medical devices produced at the Facility. The sterilization operations are subject to the federal categorical hazardous air pollutant (HAP) standard promulgated at 40 CFR Part 63, Subpart O (Subpart O), establishing maximum achievable control technology (MACT) standards for ethylene oxide (EtO) emissions from sterilization facilities.

On December 5, 2019, U.S. EPA issued an advance notice of proposed rulemaking (ANPRM) at Docket No. EPA-HQ-OAR-2019-0178, focusing on potential amendments to Subpart O. As part of the ANPRM, U.S. EPA requested comment on data contained in a modeling file intended to summarize certain EtO emissions data for existing sterilization facilities. B. Braun has reviewed the data for the Facility contained in the modeling file and has prepared a file providing necessary corrections. Please refer to the summary below.

Additionally, B. Braun also provides comments in response to specific additional information requests identified by EPA through the ANPRM.

1. CORRECTIONS TO MODELING FILE EMISSIONS INFORMATION AND ANNUAL ETO USAGE DATA

1.1 ADMINISTRATIVE CHANGES

The NAICS Code for the Facility should be corrected from 621111 (Offices of Physicians (except Mental Health Specialists)) to 339112 (Surgical and Medical Instrument Manufacturing), consistent with Facility's operations and NAICS designation for all purposes. Note, the Agency's modeling file does not allow B. Braun to make this correction directly within the modeling file.

The designations currently in the Agency's modeling file for certain existing equipment at the Facility – the Sterilization Chamber Vent, Chamber Exhaust Vent, and Aeration Room Vent – do not match the emission point information in the air quality operating permit (Permit) issued for the Facility by the Pennsylvania Department of Environmental Protection (PADEP). These designations for the Sterilization Chamber Vent, Chamber Exhaust Vent, and Aeration Room Vent should be revised to Stk – Deoxx Unit (ID S02), Common Rear Sterilizer Exhaust Stack (ID S23), and Stk – Cata. Oxidizer (ID S01), respectively, in order to match the emission point information in the Permit. Once again, the Agency's modeling file does not allow B. Braun to make this correction directly within the modeling file.

The Facility operates an additional sterilizer, Sterilizer 108, which is not listed in the Agency's current modeling file. This omission is consistent with the fact that Sterilizer 108 did not operate in 2014. B. Braun has included this sterilizer in the emissions unit descriptions within the revised modeling file, but has identified zero emissions for the source for the 2014 operating year.

1.2 NON-STERILIZATION SOURCES

Boiler – Kewanee 10.0 MMBtu/hr (Source ID 032), a non-sterilization source according to 40 CFR §63.360, is not subject to the requirements of Subpart O and has been removed from the modeling file. Boiler – Kewanee 10.0 MMBtu/hr is no longer in operation and was removed from the Facility in August 2014. B. Braun has provided notification of the unit's removal to PADEP.

1.3 STACK PARAMETERS AND CONFIGURATION

Emissions from each Sterilization Chamber Vent are combined and controlled by a single Deoxx wet scrubber, which exhausts to atmosphere through a single stack (designated as Emission Release Point ID 85372712 in the modeling file). Emissions from each sterilizer rear Chamber Exhaust Vent are combined, and exhaust to atmosphere through a separate single stack (designated as Emission Release Point ID 85373512 in the modeling file).

The modeling file included two lines for each of the seven sterilizers that operated during 2014 (i.e., one line for each Sterilization Chamber Vent and one line for each sterilizer's rear Chamber Exhaust Vent). Since all sterilizers at the Facility share the same two exhaust stacks described above, B. Braun has revised the modeling file to reflect one line for all Sterilization Chamber Vents, and one line for all sterilizer rear Chamber Exhaust Vents. (Based on this realignment and in consideration of the allocation within the modeling file of certain reported emissions as "Fugitive Emissions", B. Braun has removed from the modeling file the separate line item designated as "Fugitive Emissions".) The Aeration Room Vent, which is controlled by a catalytic oxidizer, is correctly reflected in the modeling file as a third, separate, single stack (designated as Emission Release Point ID 91627112 in the modeling file).

Stack height, exit gas temperature, stack diameter, exit gas velocity, and exit gas flow rate for the Aeration Room Vent stack and the rear Chamber Exhaust Vent stack have been revised based on

the most recent data available, which is consistent with information provided in the application for the Permit (which does not reflect any changes since 2014).

1.4 EMISSIONS CALCULATIONS

Actual emissions values were revised to reflect actual reported emissions for 2014. These calculated values are biased materially higher than probable actual emissions based on conservative factors and assumptions incorporated by B. Braun into its emissions estimation methodology. For example, the actual emissions reported for the Aeration Room Vent assume that the process operated 8,760 hours per year at the maximum capacity. In addition, consistent with Agency guidance related to the modeling file, the reported actual emissions do not correspond to current actual emissions from the Facility. B. Braun has instituted several actions since 2014 to materially reduce EtO emissions from the Facility, even when calculated using B. Braun's conservative emission estimation methodology.

B. Braun has revised the modeling file designated as "allowable emissions" consistent with guidance received from EPA regarding revisions to the modeling file. For purposes of this response, B. Braun has calculated "allowable" total emissions from the Sterilization Chamber Vents, rear Chamber Exhaust Vents and the Aeration Room Vent based on projected maximum Facility operating rates for 365 days per year. The emission estimation methodology for "allowable emissions", however, does not address all considerations relevant to the regulatory determination of Potential to Emit (PTE) under established regulatory standards. The PTE for relevant sources at the Facility are typically higher than the "allowable emissions" calculated and reported through the corrected modeling file, consistent with Agency guidance.

The modeling file also includes calculation and recording of emissions designated as "acute emissions." B. Braun does not believe that the term "acute emissions" corresponds to any specific regulatory designation applicable to its operations, nor that the Agency's determination or recording of such emission levels reflects any actual correlation to any emissions condition for the Facility. Instead, B. Braun understands that EPA calculated the "acute emissions" in the modeling file simply to correspond to a hypothetical emissions condition as a rate 20% higher than actual emissions. On this basis, B. Braun has revised the "acute emissions" values reported in the modeling file to equal the levels 20% higher than the corrected 2014 actual EtO emissions for the Sterilization Chamber Vent and Chamber Exhaust Vent now included in the modeling file. However, in correcting these values reported in the updated modeling file, B. Braun does not thereby agree that such emission levels constituted an emissions condition related to Facility operations, and does not agree that such emission levels in fact correspond to any "acute" emission rates for sources at the Facility, either for the 2014 reporting year or currently.

Supporting information related to the corrections to the reported emissions information in the modeling file is provided as Attachment A-1.

2. COMMENTS REGARDING EVALUATION AND CONTROL OF FUGITIVE EMISSIONS

Reliance on a 0.5 percent emission factor for calculation of fugitive emissions

B. Braun opposes the Agency's proposal to establish a presumptive fugitive emission rate for EtO emissions from commercial sterilization facilities of 0.5 percent of EtO usage. Not only is the specific factor arbitrary and inadequately supported by available data, the proposed approach fails to account for the relationship of fugitive emission rates to multiple facility-specific factors, notably including sterilization cycle, facility design, equipment design and use, and product and packaging materials and density.

Effective control options for fugitive emissions.

Fugitive EtO emissions from commercial sterilization operations can be most effectively controlled through robust operational practices. B. Braun employs the following measures at the Facility to effectively control fugitive emissions:

(1) In-chamber ethylene oxide cycles are run by a validated control system. Since all cycles are run below atmospheric pressure, chamber doors cannot be opened until the cycle has been successfully completed. Pressure points and cycle steps must be achieved before the cycle can proceed. Operators cannot manually circumvent the optimal cycle steps/phases.

(2) Upon cycle completion, the chamber rear door is opened in small increments and the rear Chamber Exhaust Vent activated to draw fresh air into the chamber and over the pallets, venting residual ethylene oxide to the air pollution control device (APCD).

(3) After the rear Chamber Exhaust Venting process, sterilized pallets are transferred directly from the sterilization chamber to the aeration room. This transfer process is implemented in accordance with an established operational procedure designed to minimize the potential for release of uncontrolled fugitive emissions.

(4) EtO drums are inspected for leakage upon arrival at the Facility. Upon connecting each new EtO drum to the system, the drum is subjected to leak-testing to ensure that the drum or connection will not allow unintended EtO releases (bubble spray is used to ensure the connection is leak tight). Further, the system is designed to remove all EtO from the drum before it is disconnected.

(5) Pipes used for EtO injections and removal are leak tested on a routine basis in accordance with Facility-specific Preventative Maintenance procedures.

(6) Before EtO is injected into a sterilization chamber for a sterilization cycle, the chamber is leak tested.

(7) Negative pressure is maintained within each chamber during the sterilization cycle. Therefore, if any leakage were to arise in the chamber door seal, no EtO would be released. Chamber pressure is continuously monitored to ensure that, if pressure in the chamber rises and reaches a predefined set point (less than atmospheric pressure) while EtO remains in the chamber, the system will automatically abort the cycle and begin flushing EtO out of the chamber and to the APCD.

Permanent Total Enclosures

Creation and maintenance of a permanent total enclosure (PTE) is neither necessary to effectively control fugitive EtO emissions from commercial sterilization facilities, nor feasible for many existing facilities. Method 204 establishes a design standard for consideration in the original configuration of structures and related ventilation control systems; the emission control option is not appropriate to allow equipment retrofit of existing facilities.

For example, many commercial sterilization facilities could not achieve the requisite inward air velocity specified under Method 204 even by sealing the entire sterilization area and blocking all air exhaust points which are not currently routed through an APCD. Additionally, significant ventilation changes to existing facilities can create problems with temperature control and ventilation rates. NFPA standards require that the room containing EtO drums must be located at the perimeter of the building. The NFPA-based requirements applicable to EtO drums are inconsistent with criteria governing NDO placement pursuant to Method 204.

For these and other reasons, it is not surprising that few existing commercial sterilization facilities constitute PTEs as evaluated under Method 204. In fact, the use of a PTE has not been established as a proven control technology for existing sterilization operations, and is not compatible and sustainable for routine application in this context. Instead, multiple operational control measures are available and appropriate to prevent and control fugitive EtO emissions related to commercial sterilization operations, as discussed above.

3. POLLUTION PREVENTION AND OTHER OPERATIONAL PRACTICES

Connection of sweep vents to an air pollution control device (APCD)

Consistent with many other existing commercial sterilization facilities, the APCDs installed in the Facility were designed with specific capacities to meet pre-defined objectives. Therefore, these APCDs do not have sufficient capacity to control additional flow from sweep vents which manage significant volumes of air.

Under what circumstances could EtO come into contact with water within commercial sterilization facilities?

We currently utilize a wet scrubber, where exhausted ethylene oxide from our Sterilization Chamber Vents routinely comes into contact with water. Condensation from our chambers is also sent to the wet scrubber. The wet scrubber converts ethylene oxide in water to glycol, which is then recycled for us by a third party. The water inside our wet scrubber is contained and therefore any potential emissions from the water are also contained within the system.

What is the feasibility of using additional air washes in the sterilization chamber to further decrease in-chamber EtO concentrations?

The use of additional air washes in the sterilization chamber is a viable method for reducing residual EtO inside the chamber. Extending cycle air washes not only reduces residual ethylene oxide concentration inside the chamber, but also reduces residual EtO in the product, which will in turn reduce fugitive EtO emissions resulting from off-gassing of pallets during transfer from sterilization chamber to aeration.

4. POTENTIAL USE OF CONTINUOUS EMISSION MONITORING SYSTEMS

EtO emissions are managed to extremely low concentrations. Continuous emission monitoring systems (CEMS) have generally not been utilized for APCDs controlling EtO from commercial sterilization facilities. For this and other reasons, CEMS systems have not been established as proven technology for the measurement of EtO at the extremely low concentrations relevant to controlled EtO from commercial EtO sterilization facilities. In addition, it is our understanding that only one or two vendors even supply the relevant CEMS technology.

5. ACCELERATED AERATOR DESIGN AND AERATION CELLS

For some materials, accelerated aerator cells may lessen aeration duration, which could increase process capacity. However, for many commercial sterilization operations, including the sterilization operations conducted by B. Braun Medical, implementation of accelerated aeration cells in place of traditional aeration would not impact emissions. For these many applications, any requirement to use accelerated aerator cells would impose additional operational and economic burdens without achieving any material additional reduction in EtO emissions.

We appreciate the opportunity to provide these comments regarding the Agency's ANPRM applicable to Subpart O. Should you have any questions concerning these comments or B. Braun's corrections to the modeling file, please contact Allison Longenhagen, Corporate and Internal Communications Manager, at allison.longenhagen@bbraunusa.com.

Sincerely,
B. Braun Medical Inc.

Enclosures: Attachment A-1: Supporting Information for Corrections to Modeling File

Table A-1
Actual 2014 Ethylene Oxide Emissions from Sterilizer Chambers and Aeration Room
B. Braun Medical, Inc. - Allentown, PA

2014		Total
EtO Usage (lb)		243,320
Pollutant	Emissions Factors	Emissions (tons) [a][b]
Sterilization Chamber Vent Ethylene Oxide Emissions	1.00%	1.22
Chamber Exhaust Vent Ethylene Oxide Emissions	3.43E-04 ton/cycle	1.75
Aeration Room Vent Ethylene Oxide Emissions	--	0.48
	Total Ethylene Oxide Emissions	**3.44**

[a] Emission rates from the sterilization chamber vent and aeration room vent are calculated using the EtO usage and the following information:

Scrubber Control Efficiency:	99	%[c]
Maximum EtO Concentration in Exhaust:	1.0	ppm[c]
EtO MW:	44	lb/lb-mol
Catalytic Oxidizer Rated Capacity:	16,000	cfm
Combined Sterilizer Rear Chamber Exhaust Volume:	4,000	cfm

[b] Chamber exhaust vent emission rates are calculated based on application of engineering judgment to determine the fraction of EtO that is exhausted from the back vents.

[c] As required by 40 CFR Part 63, Subpart O.